Docket 14305

Express Mail mailing label EV040215319US

Date of Deposit February 5, 2003

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SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

We, Rudolph Ehwald, Uwe Beyer and Andreas Thomas, have invented certain new and useful improvements in:

MICRO-DIALYSIS PROBE

of which the following is a specification:

Micro-dialysis Probe

BACKGROUND OF THE INVENTION

1. Technical Field.

The present invention relates to a micro-dialysis probe in accordance with the preamble of patent claim 1.

2. Description of the Related Art.

Implanted hollow fibres, hollow fibre loops or dialysis probes are used for micro-dialysis in medicine and biological research. Conventional dialysis probes possess a tube-shaped shaft in which dialysate is drained and which comprises a closed cylindrical membrane (hollow fibre sealed on one side) into whose interior a thin tube protrudes, for supplying the drip-feed solution. Between the drip-feed solution flowing back and the ambient medium, dialysis at the hollow fibre membrane leads to a concentration equalisation in the permeable substances. Probes with the same principle design are also known, in which the dialysis fibre is surrounded by a non-buckling casing or framework which it partially protrudes out from, said dialysis fibre being supported by said casing or framework. Such a dialysis probe is known, for example, from DE 33 42 170 C2.

In the use of viscous drip-feed solutions or at high flow rates in particular, it is evident that the flow through such dialysis probes is not optimal. Lateral pressure upon the probe can move the inner tube slightly out of its central position and the flow profiles via the hollow cylinder are changed. The flow can slow up or come to a standstill on the side where the gap between the outer and inner cylinder is very narrow, while a fast-flowing preferential path forms on the opposite side. Moreover, a dead space arises in the shaft in which the dialysate is drained, due to its construction, at the transfer point into the drainage tube. Both of these lead to a delay in the adjusting of the equilibrium.

To stabilise the position of the inner tube in the hollow fibre, DE 197 14 087 A1 has proposed, for such probes, surrounding the capillary with a profile. Profiles with such a small diameter and a central bore, however, can only be produced at great cost.

SUMMARY OF THE INVENTION

Correspondingly, it is the object of the present invention to propose a dialysis probe which overcomes the above-cited disadvantages of the prior art. In particular, a stable flow guidance and thus a fast adjustment of the equilibrium are to be guaranteed. Moreover, it is to be avoided that flow-impeding dead spaces arise in the dialysis area and in the supply lines and drainage lines.

This object is solved in accordance with the invention by arranging each of both the supply line and the drainage line of a micro-dialysis probe side by side on the outer wall of the probe, as separate hollow channels.

The supply line and drainage line are thus arranged side by side in accordance with the invention, not one inside the other as in the prior art. Thus, both the supply line and the drainage line each form a part of the outer wall and can thus, through their own structure or by providing protective devices formed over the corresponding channels, be stably developed such that mechanical influences do not impede the flow of the drip-feed solution. While in the prior art, for example in accordance with DE 33 42 170 C2, pressure on the outer hollow cylinder (i.e. the drainage line) automatically affects the supply line within it, this is no longer critical in the supply line and drainage line arranged side by side in accordance with the invention.

A further advantage of the dialysis probe in accordance with the invention is that the supply line and drainage line can each simply run straight in or out of the rear part of the dialysis probe, and flow redirection – in which dead spaces are formed – can be largely avoided.

In an embodiment of the micro-dialysis probe in accordance with the invention, the first drainage line in the direction of the flow consists of a dialysis hollow fibre penetrating into the supply line behind the inversion, the hollow fibre being fastened in the area of the sealed tip of the probe such that a linear course of flow is achieved after the inversion, while at its other end it is sealed into a second stable section of the drainage line. In this way, the drip-feed solution flows through the whole cross-section of the dialysis hollow fibre in

one direction, and the dialysate is introduced into the drainage line linearly, without a change in direction. The flow direction is here inverted, as is necessary to enable the liquid to be supplied and drained from one side, before it enters the dialysis hollow fibre, such that the dialysis itself is not impeded by disturbances in the flow. The previously mentioned stable section is preferably a tube which forms the outer part of the drainage line, i.e. its supporting component. In this way, the part of the tube in the area of the tip of the probe which lies over the hollow fibre, where the dialysis hollow fibre penetrates into the supply line, can form a supporting section to mechanically strengthen this part of the probe.

The hollow fibre is preferably formed to be replaceable, and correspondingly sealed in, the tube and in particular its supporting section comprising recesses via which the hollow fibre is exposed outwards, to be able to perform dialysis. In this way, the supply line, and the supporting section arranged on the opposite side of the hollow fibre parallel to said supply line, form an outer framework which mechanically shields the hollow fibre from the surrounding matrix of tissues without preventing direct liquid contact between the hollow fibre and the surrounding medium. The supply line and the drainage line can in principle be separate parts, connected firmly at the tip and the side facing away from it, when assembled. However, it is particularly favourable if the supply line and the drainage line, which comprise a flow connection in their tip, are integrated into a single piece, for example via a fixing material.

In a further preferred embodiment of the micro-dialysis probe in accordance with the invention, the flow channel for the drip-feed solution consists of a hollow fibre with a supporting profile inserted into it which separates the supply line and the drainage line from each other, the supporting profile comprising overflow openings in the area of flow inversion. Here too, therefore, the principle is again realised that each of the supply line and the drainage line form, together with the hollow fibre, a part of the outer wall of the probe, but are separated and supported in such a way that the flow is not impeded. In this way, both the supporting function and flow guidance are assumed by the profile. The supporting profile is thus designed in accordance with the invention such that the volume of the hollow fibre through which the flow may pass consists of a number of elongated hollow spaces. These hollow spaces enable the drip-feed agent to flow into the tip of the probe and to be re-circulated to the other side, wherein the flow is inverted by the overflow openings. Here, too, the flow in and out can largely be achieved in a straight course of flow.

An embodiment of the micro-dialysis probe as described above is preferred developed such that the hollow fibre at the supply line end and drainage line end of the probe is sealed into a probe shaft which

accommodates and continues the supply line and the drainage line separately. Such a probe shaft ensures a further increase in stability and enables the necessary connections to be provided.

The supporting profile can be developed with a star-shaped cross-section, for example as a three- or four-armed star. On the other hand, however, it is also possible to form the profile as a flat partition which exhibits a rectangular or lenticular cross-section and is provided on one or both of its flat sides with fine bristles or knobs which keep the hollow fibre wall at a distance.

The greatest mechanical stability, however, is achieved using a star profile. In the case of a four-armed star profile, the drip-feed solution is guided in two parallel channels as the supply line, while the other two channels form the drainage line. If a three-armed star profile is used, the stretching of the hollow fibre material caused by swelling can be compensated for, if the dry hollow fibre is moved taut over the profile and appears in cross-section like a triangle with rounded corners. When the hollow fibre membrane is stretched, this again forms a circle in cross-section. In this three-armed embodiment of the profile, a single supply line is accordingly provided, but two drainage lines. Since the hollow fibre is sufficiently supported from within, it can be exposed to the matrix of tissues along its entire length. Dialysis then takes place both in the supply line as well as in the drainage lines.

Although a higher flow rate prevails in the individual supply line due to the smaller cross-section, an efficient exchange of material take also take place here, since the concentration gradient between the drip-feed solution and the surroundings is still at its greatest in this area. After the drip-feed solution has overflowed into the two parallel drainage lines in the immediate vicinity of the tip, the flow rate is halved, which promotes concentration equalisation between the substances passing through the hollow fibre, since more time is available for this purpose.

The supply line and/or drainage line of a micro-dialysis probe in accordance with the invention should preferably have a substantially linear course, to largely rule out the formation of dead spaces in the flow.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be explained in more detail by way of two preferred embodiments. There is shown:

Figure 1 a first embodiment of a micro-dialysis probe in accordance with the invention, in a longitudinal sectional view with two cross-sectional views; and

Figure 2 a second embodiment of a micro-dialysis probe in accordance with the invention, in a longitudinal sectional view with four cross-sectional views.

DETAILED DESCRIPTION

The micro-dialysis probe shown in Figure 1 consists of a supply channel, namely a supply line 1, through which the drip-feed solution is introduced into the probe. On its other side, the probe is sealed and pointed with a sealing material 13, to enable it to be introduced into subcutaneous tissue. In the vicinity of the tip of the probe, the hollow fibre 4 penetrates from above into an opening 10 of the supply line 1. This flow connection is formed with the aid of the shaping of the sealing material, such that the flow can be inverted without being substantially impeded. On the other hand, the hollow fibre 4 in the surroundings of the opening 10 is sealed in with the aid of the sealing material, such that there is no leakage.

After the flow has been inverted, the hollow fibre 4 forms the dialysis section. To this end, the tube 11 surrounding the drainage line 6 is provided with recesses 5 in the area of the cross-section shown on the left, such that the hollow fibre 4 is here exposed to the surrounding tissue and dialysis can take place.

Only one supporting section 3 of the tube 11 lies over the hollow fibre 4 in this area, to shield said fibre on this side from mechanical pressure from without.

In its further course towards the right end of the drainage line 6, the hollow fibre 4 is then again completely surrounded by the tube 11, as follows from the cross-section shown on the right. In this area, it is sealed in by means of a carrier material (shown in grey) in the tube 11. The supply line 1 and the drainage line 6 with the surrounding tube 11 are fixed to each other in this area using the fixing material 9 which is most easily recognised in the cross-section shown on the right. The dialysis probe thus forms an integral unit.

When considering this embodiment of the micro-dialysis probe in accordance with the invention, as it is shown in Figure 1, it then becomes clear on the one hand that no dead spaces, which could impede the flow and delay adjustment of the equilibrium, are created in the course of the flow, in particular during the supply and drainage of the drip-feed solution. On the other hand, it is clearly shown that arranging the

supply line 1 and the drainage line 6 side by side allows a very stable probe to be formed, in which even external mechanical effects can hardly interrupt the continuity of the flow. In short, both the supply line and the drainage line can also be mechanically well protected, since these parts are at least mostly arranged parallel on the outer wall of the probe. In supply lines accommodated in the drainage line, as previously provided by the prior art, this is not possible or only at very great cost.

Figure 2 shows a second micro-dialysis probe in another embodiment. In this construction, the supply line channel 1 and drainage line channel 6 lie, at the supply line end and drainage line end of the probe, in a probe shaft 12, where inserted hoses 14 and 15 are arranged. The three-armed star-shaped profile 2 is attached to the left front face of the shaft 12, over which the hollow fibre 8 is pulled and sealed at the point of attachment. The supply line 1 and the drainage line 6 are still formed in the area of the shaft 12 by the shaft itself, as follows from the cross-section shown on the far right. The cross-section second from right then shows how a lower supply line 1 and two upper drainage lines 6 are formed by the profile 2 covered by the hollow fibre 8. The supply line 1 and the drainage line 6 are separated from each other towards the tip area up to the front, and run parallel. The cross-section second from left then shows that the middle piece of the profile 2 is left open at this point, such that an overflow opening 7 is created through which the drip-feed liquid can flow from the supply line 1 into the drainage lines 6. Thus, in this embodiment, flow inversion takes place here. The profile is sealed together with the hollow fibre at the tip by a sealing material 13, as can be seen in the cross-section on the left. Having passed the overflow opening 7, the drip-feed liquid then flows back in the two drainage lines 6, which re-unite in the area of the shaft. Here, too, the supply line and the drainage lines run side by side and are supported from within by the profile 2, such that impedance of the flow through external influences can be largely ruled out. Furthermore, it is also clear in this example that the flow is substantially linear and is guided in a straight line over wide stretches, such that dead spaces and the impedance of the flow and delays in adjusting the equilibrium connected with them are avoided.

Dialysis takes place along the entire section of the hollow fibre 8, from the shaft 12 up to the sealing material 13, both in the supply line 1 and in the drainage lines 6. Because of the smaller cross-section, the solution admittedly flows faster in the supply line 1, however the highest concentration gradient is also present in this area, such that sufficient dialysis takes place. This concentration gradient is admittedly lower in the two drainage line sections, however the contact area here is even greater and the flow rate is only a half, such that an effective concentration equalisation can also be achieved in this area. Components 14

and 15 can be developed as supply and drainage hoses respectively, and simply sealed into the shaft at their insertion points, such that the solution is prevented from escaping.

In the foregoing description preferred embodiments of the invention have been presented for the purpose of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described to provide the best illustration of the principals of the invention and its practical application, and to enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the appended claims when interpreted in accordance with the breadth they are fairly, legally, and equitably entitled.